K113546

JUL 24 2012

510(k) Summary

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitter Name, Address, Contact

Roche Diagnostics
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Contact Person: Michael Leuther, PhD, MBA

Date Prepared: July 18, 2012

Device Name

Proprietary name:	(1) Elecsys Vitamin D Assay (2) Elecsys Vitamin D CalSet (3) Elecsys PreciControl Varia 3 (4) Elecsys Vitamin D CalCheck 5
Common name:	(1) Vitamin D Assay (2) Vitamin D Calibrator (3) Vitamin D Control (4) Vitamin D CalCheck 5
Classification name:	(1) System, Test, Vitamin D (2) Calibrator, Secondary (3) Multi-analyte controls, all kinds (Assayed and Unassayed) (4) Single (specified) analyte controls (Assayed and Unassayed

Continued on next page

510(k) Summary, Continued

Device Description

(1) The Elecsys Vitamin D Assay is a competitive protein binding assay which uses Vitamin D Binding Protein instead of monoclonal antibodies for detection of 25-Hydroxyvitamin D. The total duration of the assay is 27 minutes. The sample is treated with pretreatment reagent in the first incubation period. This releases any vitamin D from the endogenous vitamin D binding protein present in the patient's sample. In the next incubation, vitamin D binding protein labeled with ruthenium is added and a complex is formed between the vitamin D (25-OH) and the ruthenylated vitamin D binding protein. In the 3rd and final incubation, streptavidin-coated microparticles are added along with vitamin D (25-OH) labeled with biotin. Any unbound ruthenium labeled vitamin D binding proteins become occupied with biotin-labeled vitamin D (25-OH). The complex consisting of the ruthenylated vitamin D binding protein and the biotinylated vitamin D (25-OH) becomes bound to the solid phase via interaction of the biotin and streptavidin. The reaction mixture is aspirated into the measuring cell where the electrochemiluminescence emission is detected. Results are determined using a calibration curve that is generated specifically on each instrument by a 2 point calibration provided with the reagent bar code.
(2) The Elecsys Vitamin D CalSet is a lyophilized product based on human serum. It has been standardized against LC-MS/MS, which has in turn been standardized to the NIST standard. .
(3) The Elecsys PreciControl Varia 3 is a multi-composite lyophilized 3 level control set which has been previously cleared for 7 components . The Elecsys PreciControl Varia 3 has been cleared under K111506 for the following analytes:

Assay Name	FDA Clearance Number for Reagents
Vitamin B12	K060755
Ferritin	K971833
Folate III	K082340
βCrossLaps/Serum (-CTx)	K993706
Osteocalcin	K051297
Parathyroid Hormone	K070709
Parathyroid Hormone Short Turnaround Time (PTH-STAT)	K070709

(4) The Elecsys Vitamin D CalCheck 5 contains 5 lyophilized levels based on human serum.

Note: The reagent, calibrator, and the quality control materials are all packaged separately.

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510(k) Summary, Continued

Intended Use/Indications for Use

- **Elecsys Vitamin D Reagent:**
  The Elecsys Vitamin D assay is intended for the quantitative determination of total 25-hydroxyvitamin D in human serum and plasma. The assay is to be used as an aid in the assessment of vitamin D sufficiency in adults.
  The electrochemiluminescence binding assay is intended for use on Elecsys and **cobas e** immunoassay analyzers.

- **Elecsys Vitamin D CalSet:** Elecsys Vitamin D CalSet is used for calibrating the quantitative Elecsys Vitamin D assay on the Elecsys and **cobas e** immunoassay analyzers.

- **Elecsys PreciControl Varia 3:** Elecsys PreciControl Varia 3 is used for quality control of the specified Elecsys immunoassays on the Elecsys and **cobas e** immunoassay analyzers.

- **Elecsys Vitamin D CalCheck 5:** The Elecsys Vitamin D CalCheck 5 is an assayed control for use in calibration verification and for use in the verification of the assay range established by the Elecsys Vitamin D reagent on the indicated Elecsys and **cobas e** immunoassay analyzers.

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510(k) Summary, Continued

Substantial Equivalence

The Elecsys Vitamin D Test System is substantially equivalent to other devices legally marketed in the United States.

(1) Elecsys Vitamin D Assay is equivalent to the Abbott Architect 25-OH Vitamin D assay (K110619).

(2) Elecsys Vitamin D CalSet is equivalent to the standards contained in the Elecsys hGH CalSet (K103221) (Human Growth Hormone).

(3) Elecsys PreciControl Varia 3 is equivalent to the controls contained in the PreciControl Multimarker (K102157).

(4) The Elecsys Vitamin D CalCheck 5 is equivalent to the Elecsys T4 CalCheck 5 (K112528).

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Premarket Notification, 510(k) for Elecsys Vitamin D Test System

Substantial Equivalence - Comparison

The following table compares the Elecsys Vitamin D Test System with the predicate device. The next three tables compare the Elecsys Vitamin D CalSet, CalCheck 5, and PreciControl Varia 3 to their predicates.

Comparison of Assays, Similarities and Differences

Premarket Notification, 510(k) for Elecsys Vitamin D Test System

Assay Comparison		
Feature	**Elecsys Vitamin D Assay**	**Predicate Device: Abbott Architect 25-OH Vitamin D (K110619)**
General Assay Features		
Intended Use/ Indications for Use	The Vitamin D assay is intended for the quantitative determination of total 25-hydroxyvitamin D in human serum and plasma. This assay is to be used as an aid in the assessment of vitamin D sufficiency in adults. The electrochemiluminescence binding assay is intended for use on Elecsys and **cobas e** immunoassay analyzers.	The Abbott Architect 25-OH Vitamin D assay is a chemiluminescent microparticle immunoassay (CMIA) for the quantitative determination of 25-hydroxyvitamin D (25-OH vitamin D) in human serum or plasma. The Architect 25-OH Vitamin D assay is to be used as an aid in the assessment of vitamin D sufficiency.
Assay Protocol	Quantitative protein binding assay	Quantitative chemiluminescence immunoassay
Detection Protocol	Electrochemiluminescence	Chemiluminescence
Applications	27 minute application	36 minutes (time to first result)

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Premarket Notification, 510(k) for Elecsys Vitamin D Test System, Continued

Comparison of Assays—Similarities and Differences, continued

Assay Comparison		
Feature	**Elecsys Vitamin D Assay**	**Predicate Device: Abbott Architect 25-OH Vitamin D (K110619)**
General Assay Features		
Instrument Platform	Elecsys 2010 and **cobas e** 411	Abbott Architect 25-OH Vitamin D
Sample Volume	15 µL	60 µL for first run, 10 µL for additional runs
Sample Type	Human serum and plasma treated with K_2-EDTA, K_3-EDTA or lithium heparin.	Human serum, plasma treated with lithium heparin, sodium heparin, potassium EDTA, or sodium citrate.
Reagents	The Elecsys Vitamin D assay is a competitive binding assay which includes vitamin D (25-OH) labeled with biotin, and a ruthenium labeled vitamin D binding protein, and streptavidin coated microparticles.	The Abbott Architect 25-OH Vitamin D assay is a competitive one-step delayed immunometric assay which includes anti-vitamin D coated microparticles, an assay diluent, and biotinylated vitamin D anti-biotin acridinium labeled conjugate.
Calibrator	Elecsys Vitamin D CalSet, 2 levels	Architect 25-OH Vitamin D Calibrators, 6 levels

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Premarket Notification, 510(k) for Elecsys Vitamin D Test System, Continued

Comparison of Assays—Similarities and Differences, continued

Assay Comparison		
Feature	**Elecsys Vitamin D Assay**	**Predicate Device: Abbott Architect 25-OH Vitamin D (K110619)**
General Assay Features		
Calibration Interval	Calibration must be performed once per reagent lot using fresh reagent (i.e. not more than 24 hours since the reagent kit was registered on the analyzer). Renewed calibration is recommended as follows: • After 1 month (28 days) when using the same reagent lot. • After 7 days (when using the same reagent kit on the analyzer). • As required: e.g. quality control findings outside the specified limits	Calibration must be performed: • After 7 days • When a control value is out of range
Controls	Elecsys PreciControl Varia 3	Architect 25-OH Vitamin D Controls

Continued on next page

Premarket Notification, 510(k) for Elecsys Vitamin D Test System, Continued

Comparison of Assays—Similarities and Differences, continued

Assay Comparison		
Feature	**Elecsys Vitamin D Assay**	**Predicate Device: Abbott Architect 25-OH Vitamin D (K110619)**
General assay features		
Traceability / Standardization	The Elecsys Vitamin D Assay has been standardized against LC-MS/MS which in turn has been standardized to the NIST standard.	Architect 25-OH Vitamin D is traceable to a manufacturer's internal standard (Primary Calibrator), which is anchored against Absorbance at 264 nm.
Reagent Stability	Unopened at 2-8 °C—up to stated expiration date After opening at 2-8 °C—56 days On the Elecsys 2010 and **cobas e** 411—21 days	Unopened at 2-8 °C—up to stated expiration date. After opening: on-board the analyzer for 14 days

Continued on next page

Premarket Notification, 510(k) for Elecsys Vitamin D Test System, Continued

Comparison of Assays—Similarities and Differences, continued

Assay Comparison		
Feature	**Elecsys Vitamin D Assay**	**Predicate Device: Abbott Architect 25-OH Vitamin D (K110619)**
Labeled Performance Characteristics		
Measuring Range	5-60 ng/mL	13-96 ng/mL
Precision	*Elecsys 2010/ cobas e 411:* Within-run (will be labeled Repeatability) n=84, human sera 7.2% CV @ 6.2 ng/mL 5.1% CV @ 11.2 ng/mL 2.9% CV @ 23.2 ng/mL 2.4% CV @ 45.3ng/mL 1.6% CV @ 52.6 ng/mL Total (will be labeled Intermediate) 10.3% CV @ 6.2 ng/mL 7.6% CV @ 11.2 ng/mL 5.3% CV @ 23.2 ng/mL 3.4% CV @ 45.3ng/mL 2.9% CV @ 52.6 ng/mL	*Abbott Architect 25-OH Vitamin D* Within-run n=80, human sera 3.1% CV @ 23.0 ng/mL 2.6% CV @ 42.5 ng/mL 1.4% CV @ 75.4 ng/mL Total 4.0% CV @ 23.0 ng/mL 3.2% CV @ 42.5 ng/mL 2.7% CV @ 75.4 ng/mL

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Premarket Notification, 510(k) for Elecsys Vitamin D Test System, Continued

Comparison of Assays—Similarities and Differences, continued

<table>
<tr><th colspan="3">Assay Comparison</th></tr>
<tr><th>Feature</th><th>Elecsys Vitamin D Assay</th><th>Predicate Device: Abbott Architect 25-OH Vitamin D (K110619)</th></tr>
<tr><th colspan="3">Labeled Performance Characteristics</th></tr>
<tr><td>Analytical Sensitivity</td><td>Limit of Blank (LoB) 2.00 ng/mL
Limit of Detection (LoD) 3.00 ng/mL
Limit of Quantitation (LoQ) 5.00 ng/mL</td><td>Limit of Blank: 1.9 ng/mL
Limit of Detection: 3.1 ng/mLL
Limit of Quantitation (LoQ) 8.0 ng/mL</td></tr>
<tr><td>Analytical Specificity</td><td><table><tr><th>Cross Reactant</th><th>Cross Reactivity (%)</th></tr><tr><td>25-hydroxyvitamin D3</td><td>100</td></tr><tr><td>25-hydroxyvitamin D2</td><td>92</td></tr><tr><td>24,25-hydroxyvitamin D3</td><td>149</td></tr><tr><td>1,25-hydroxyvitamin D3</td><td>not detected</td></tr><tr><td>1,25-hydroxyvitamin D2</td><td>not detected</td></tr><tr><td>Vitamin D3</td><td>not detected</td></tr><tr><td>Vitamin D2</td><td>not detected</td></tr><tr><td>C3-epimer of 25-hydroxyvitamin D3</td><td>91</td></tr></table></td><td><table><tr><th>Cross Reactant</th><th>Cross Reactivity (%)</th></tr><tr><td>25-hydroxyvitamin D3</td><td>105</td></tr><tr><td>25-hydroxyvitamin D2</td><td>82</td></tr><tr><td>24,25-hydroxyvitamin D3</td><td>112</td></tr><tr><td>1,25-hydroxyvitamin D3</td><td>12.6</td></tr><tr><td>1,25-hydroxyvitamin D2</td><td>Not tested</td></tr><tr><td>Vitamin D3</td><td>0.3</td></tr><tr><td>Vitamin D2</td><td>0.1</td></tr><tr><td>C3-epimer of 25-hydroxyvitamin D3</td><td>2.7</td></tr></table></td></tr>
<tr><td>Hook Effect</td><td>There is no high-dose hook effect since the Elecsys Vitamin D assay is a competitive assay</td><td>Unknown</td></tr>
<tr><td>Limitations</td><td>The assay is unaffected by:
Hemoglobin < 2 g/L
Bilirubin up ≤ 66 mg/dL
Lipemia < 400 mg/dL
Biotin < 70 ng/mL
HAMA and Rheumatoid factors were not assessed because the assay does not utilize antibodies</td><td>The assay is unaffected by:
Hemoglobin <200 mg/dL
Bilirubin up < 20 mg/dL
Triglycerides < 5000 mg/dL
Biotin not tested
HAMA<1000 ng/mL
Rheumatoid Factor <400 IU/mL</td></tr>
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Premarket Notification, 510(k) for Elecsys Vitamin D Test System, Continued

Comparison of Assays—Similarities and Differences, continued

<table>
<tr><th colspan="3">Assay Comparison</th></tr>
<tr><th>Feature</th><th>Elecsys Vitamin D Assay</th><th>Predicate Device: Abbott Architect 25-OH Vitamin D (K110619)</th></tr>
<tr><th colspan="3">Labeled Performance Characteristics</th></tr>
<tr><td>Method Comparison (LC-MS/MS vs. Elecsys)</td><td colspan="2"><table>
<tr><th></th><th>Slope</th><th>Intercept</th><th>r</th></tr>
<tr><td>Deming(n=290)</td><td>1.03</td><td>-3.07</td><td>0.85</td></tr>
</table></td></tr>
<tr><td>Method Comparison Abbott vs. Elecsys)</td><td colspan="2"><table>
<tr><th></th><th>Slope</th><th>Intercept</th><th>r</th></tr>
<tr><td>Deming(n=165)</td><td>0.99</td><td>1.20</td><td>0.91</td></tr>
</table></td></tr>
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Premarket Notification, 510(k) for Elecsys Vitamin D Test System, Continued

Comparison of CalSet Materials

Characteristic	CalSet for Elecsys Vitamin D Assay	Predicate Device: Elecsys hGH CalSet (K103221)
Intended Use	Elecsys Vitamin D CalSet is used for calibrating the quantitative Elescys Vitamin D assay on the Elecsys and **cobas e** immunoassay analyzers.	Elecsys hGH CalSet is used for calibrating the quantitative Elecsys hGH assay on the Elecsys and **cobas e** immunoassay analyzers.
Levels	Two	Same
Matrix	Human serum	Same
Format	Lyophilized	Same
Stability	Unopened: • Store at 2 - 8°C up to the stated expiration date. After reconstitution: • At 2 - 8°C: 120 hours • At -20°C: 90 days (freeze only once). • On Elecsys 2010/**cobas** e 411 at 20 - 25°C: Up to 5 hours.	Unopened: • Store at 2 - 8°C up to the stated expiration date. After reconstitution: • At 2 - 8°C: 7 days • At -20°C: 28 days (freeze only once). • On Elecsys 2010/**cobas** e 411 at 20 - 25°C: Up to 5 hours. On MODULAR ANALYTICS E170/**cobas** e 601: Use only once.
Handling	Dissolve the contents of one bottle carefully by adding exactly 1.0 mL of distilled water and allow to stand closed for 15 minutes to reconstitute. Mix carefully, avoiding the formation of foam. Transfer the reconstituted calibrator into the empty labeled snap-cap bottles supplied.	Dissolve carefully the contents of one bottle by adding exactly 1.0 mL of distilled or deionized water and allow to stand closed for 15 minutes to reconstitute. Mix carefully, avoiding the formation of foam. Transfer the reconstituted calibrator into the empty labeled snap-cap bottle supplied.

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Premarket Notification, 510(k) for Elecsys Vitamin D Test System, Continued

Comparison of PreciControl Materials

Characteristic	Elecsys PreciControl Varia 3	Predicate Device: Elecsys PreciControl Multimarker (K102157)
Intended Use	Elecsys PreciControl Varia 3 is used for quality control of Elecsys immunoassays on the Elecsys and **cobas e** immunoassay analyzers.	Elecsys PreciControl Multimarker is used for quality control of specified Elecsys immunoassays on the Elecsys and **cobas e** immunoassay analyzers.
Levels	Three	Two
Format	Lyophilized	Same
Matrix	Human serum	Equine serum
Analyte Concentration	25-hydroxyvitamin D (synthetic) in human serum at target values of approximately: V3 0: 12.8 ng/mL V3 1: 17 ng/mL V3 2: 32 ng/mL	C-Peptide (synthetic): Approximately 2 and 10 ng/mL. Insulin (human recombinant from yeast): Approximately 25 and 80 µU/mL. ACTH (synthetic): Approximately 50 and 1,000 pg/mL. hGH (human recombinant from E. *coli*): Approximately 1 and 10 ng/mL.
Stability	Unopened: • Store at 2-8°C up to the stated expiration date Reconstituted: • 2 - 8°C: 72 hours • -20°C: 31 days(freeze only once) • On the analyzers at 20-25°C: up to 5 hours	Unopened: • Store at 2-8°C up to the stated expiration date Reconstituted: • 2 - 8°C: 72 hours • -20°C: 31 days (freeze only once) • On the analyzers at 20-25°C: up to 5 hours
Handling	Carefully dissolve the contents of one bottle by adding exactly 3.0 mL of distilled or deionized water and allow to stand closed for 30 minutes to reconstitute. Mix carefully, avoiding the formation of foam. Transfer the reconstituted control into the empty, labeled snap-cap bottles supplied or freeze aliquots in additional snap-cap bottles (ControlSet Vials). Attach the supplied labels to these bottles. Perform **only one** control procedure per aliquot.	Dissolve carefully the contents of one bottle by adding exactly 2.0 mL of distilled or deionized water and allow to stand closed for 30 minutes to reconstitute. Mix carefully, avoiding the formation of foam. Transfer the reconstituted control into empty, labeled snap-cap bottles supplied (ControlSet Vials) and freeze aliquots immediately in additional ControlSet Vials. Attach the supplied labels to these additional bottles. Perform **only one** control procedure per aliquot.

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Premarket Notification, 510(k) for Elecsys Vitamin D Test System, Continued

Comparison of CalCheck 5 Materials

Characteristic	Elecsys Vitamin D CalCheck 5	Predicate Device: Elecsys T4 CalCheck 5 (K112528)
Intended Use	The Elecsys Vitamin D CalCheck 5 is an assayed control for use in calibration verification and for use in the verification of the assay range established by the Elecsys Vitamin D reagent on the indicated Elecsys and **cobas e** immunoassay analyzers.	The Elecsys T4 CalCheck 5 is an assayed control for use in calibration verification and for use in the verification of the assay range established by the Elecsys T4 reagent on the indicated Elecsys and **cobas e** immunoassay analyzers.
Analyte	(25-OH) Vitamin D	Thyroxine (T4)
Levels	Five	Same
Matrix	Human serum	Check 1: BSA/Buffer matrix Check 2-5: human serum
Format	Lyophilized	Same
Handling	Reconstitute Check 1, Check 2, Check 3, Check 4 and Check 5 with exactly 1.0 mL distilled or deionized water. Allow to stand closed for 15 minutes, then mix gently by inversion to ensure homogeneity.	Same
Stability	Unopened: • Store at 2-8 °C until expiration date Reconstituted: • 20-25 °C: 5 hours	Same

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

JUL 24 2012

Roche Diagnostics
c/o Michael Leuther, PhD, MBA
Roche Professional Diagnostics
9115 Hague Road
Indianapolis, IN 46250

RE: k113546
Trade Name: Elecsys Vitamin D Assay
Elecsys Vitamin D CalSet
Elecsys PreciControl Varia 3
Elecsys Vitamin D Calchek 5
Regulation Number: 21 CFR §862.1825
Regulation Name: Vitamin D test system
Regulatory Class: Class II
Product Codes: MRG, JIT,JJY,JJX
Dated: July 5, 2012
Received: July 6, 2012

Dear Dr. Leuther:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): _____

Device Name: Elecsys Vitamin D Assay

Indications for Use:

The Elecsys Vitamin D assay is intended for the quantitative determination of total 25-hydroxy vitamin D in human serum and plasma. The Elecsys Vitamin D assay is to be used as an aid in the assessment of vitamin D sufficiency in adults.

The electrochemiluminescence binding assay is intended for use on Elecsys and **cobas e** immunoassay analyzers.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K113546

Indications for Use Form

510(k) Number (if known): _____

Device Name: Elecsys Vitamin D CalSet

Indications for Use: Elecsys Vitamin D CalSet is used for calibrating the quantitative Elecsys Vitamin D assay on the Elecsys and **cobas e** immunoassay analyzers.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K113546

Indications for Use Form

510(k) Number (if known): _____

Device Name: Elecsys PreciControl Varia 3

Indications for Use: Elecsys PreciControl Varia 3 is used for quality control of specified Elecsys immunoassays on Elecsys and **cobas e** immunoassay analyzers.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K113546

Indications for Use Form

510(k) Number (if known): _____

Device Name: Elecsys Vitamin D CalCheck 5

Indications for Use: The Elecsys Vitamin D CalCheck 5 is an assayed control for use in calibration verification and for use in the verification of the assay range established by the Elecsys Vitamin D reagent on the indicated Elecsys and **cobas e** immunoassay analyzers.

Prescription Use __X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
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